MEDICAL POLICY

POLICY TITLE	FUNCTIONAL ENDOSCOPIC SINUS SURGERY FOR CHRONIC RHINOSINUSITIS
POLICY NUMBER	MP-1.152

Original Issue Date (Created):	**8/1/2018**
Most Recent Review Date (Revised):	**2/14/2019**
Effective Date:	**4/1/2019**

I. POLICY

The use of functional endoscopic sinus surgery in the treatment of chronic rhinosinusitis is considered **medically necessary** for patients with chronic rhinosinusitis when the following criteria are present:

1. Chronic rhinosinusitis symptoms, characterized by at least 2 of the following, at least 1 of which is (a) or (b), are present for at least 12 continuous weeks:
   a. Mucopurulent nasal drainage;
   b. Nasal congestion;
   c. Facial pain;
   d. Facial pressure;
   e. Anosmia or hyposmia.

   AND

2. Appropriate medical therapy has been attempted, including all of the following:

   a. Topical nasal steroids for at least 8 consecutive weeks;
   b. Nasal lavage for at least 8 consecutive weeks;
   c. Consideration for allergic and/or immune evaluation if the patient has symptoms consistent with allergic rhinitis and/or immunodeficiency.

   AND

3. There is objective evidence of mucosal inflammation as demonstrated by one of the following:

   a. Sinus computed tomography or magnetic resonance imaging showing significant mucosal thickening or opacification of the paranasal sinuses; OR
   b. Nasal endoscopy with purulent mucus in the middle meatus or ethmoid region OR polyps in the nasal cavity or middle meatus.

   AND

4. There are no serious urgent complications of acute sinusitis that would suggest orbital cellulitis or abscess, intracranial extension of infection, or other complication that would require urgent or emergent surgery such that "appropriate medical therapy" for 8 weeks would not be appropriate.

The use of functional endoscopic sinus surgery is considered **investigational** for the treatment of chronic rhinosinusitis when the above criteria are not met. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Criteria for "maximal medical therapy" used before endoscopic sinus surgery is attempted have been reported in a minority (21%) of published studies of endoscopic sinus surgery (Dautremont & Rudmik, 2015). The criteria used vary across studies, but studies that have reported specific criteria most often report using topical steroids (91.4%; mean duration, 8.4 weeks) and oral antibiotics (87.7%; mean duration, 23 days) (Dautremont & Rudmik, 2015). Systematic reviews of randomized controlled trials have consistently demonstrated improved symptoms of chronic rhinosinusitis with topical steroids. In contrast, weak evidence supports the use of systemic antibiotics in chronic rhinosinusitis.

Cross-reference:

MP 1.119 - Balloon Ostial Dilation for the Treatment of Chronic Rhinosinusitis
MP 1.140 - Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease

II. PRODUCT VARIATIONS TOP

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

III. DESCRIPTION/BACKGROUND TOP

Chronic rhinosinusitis (CRS) is a common chronic condition associated with significant morbidity. Functional endoscopic sinus surgery (FESS) involves the removal of varying amounts of tissue and the opening of sinus ostia to treat CRS in individuals who have failed medical therapy.

CHRONIC RHINOSINUSITIS

Chronic rhinosinusitis (CRS) is a highly prevalent inflammatory disorder of the paranasal sinuses and the mucosa of the nasal passages that affects 3% to 7% of adults.[1] In adults, CRS is characterized by symptoms related to nasal and sinus obstruction and inflammation,

including mucopurulent nasal drainage, nasal congestion, facial pain or pressure, and anosmia or hyposmia, that persist for at least 12 weeks.

Three CRS subtypes exist, and may have somewhat different treatment strategies: CRS without nasal polyposis; CRS with nasal polyposis; and allergic fungal sinusitis. The latter is a less common subtype thought to result from chronic allergic inflammation to colonizing nasal fungi. This policy focuses on the more common subtypes: CRS with and without nasal polyposis. Both subtypes present with similar symptoms. However, CRS with nasal polyposis is, by definition, associated with nasal polyps that are visible on rhinoscopy or nasal endoscopy. Further, CRS with nasal polyposis is more likely to be associated with asthma and aspirin intolerance; this triad is referred to as Samter syndrome or aspirin-exacerbated respiratory disease.

CRS is associated with impaired quality of life (QOL) for affected patients, and with high direct and indirect costs for medical treatments and lost productivity. Most often, the negative health effects of CRS are related to the unpleasant symptoms associated with CRS, including nasal congestion, nasal drainage, and facial pain or pressure. In rare cases CRS can be associated with serious complications, including orbital cellulitis, osteomyelitis, or intracranial extension of infection.

While acute sinusitis is considered a more traditional infectious process, CRS is a chronic inflammatory disease of the upper airways, with multiple underlying causes. Risk factors for CRS with or without nasal polyps include anatomic variations and gastroesophageal reflux. There are conflicting reports about the association between allergy and CRS without nasal polyps, although weak evidence has suggested that allergy may be associated with CRS with nasal polyps. In addition, aspirin sensitivity may be associated with CRS with nasal polyps. The role of bacterial, viral, and fungal microorganisms in CRS has been actively investigated. There is some evidence that CRS is associated with a predominance of anaerobic bacteria.[2,3] On the other hand, 1 study that used bacterial ribosomal RNA sequencing to evaluate the sinus microbiome in patients with and without CRS found a quantitative increase in bacterial and fungal RNA expression in patients with CRS, but no major differences in the types of microorganisms detected.[4] Bacterial biofilms have been identified in cases of CRS.[5]

Diagnostic Criteria

Several medical organizations have developed criteria for the diagnosis of CRS, which are summarized in Table 1. Most diagnostic schema require the presence of the major symptoms of CRS for more than 12 weeks, combined with objective evidence of mucosal inflammation on sinus imaging, endoscopy or rhinoscopy, or both.

Table 1. Chronic Rhinosinusitis Diagnostic Criteria

Organization	Chronic Rhinosinusitis Definition
International Consensus Statement on Allergy and Rhinology: Rhinosinusitis (2016)[6]	"Sinonasal inflammation persisting for more than 12 weeks. Symptoms must include at least 2 of the following: • Nasal blockage/obstruction/congestion • Nasal discharge (anterior/posterior) • Facial pain/pressure • Reduction/loss of smell" "Additionally, the diagnosis must be confirmed by: • Evidence of inflammation on paranasal sinus examination or computed tomography (CT) • Evidence of purulence coming from paranasal sinuses or ostiomeatal complex." "CRS is divided into CRSwNP or CRSsNP based on the presence or absence of nasal polyps"
American Academy of Allergy, Asthma, and Immunology et al (2005)[7]	"Symptoms for 8 weeks or longer of varying severity consisting of the same symptoms as seen in acute sinusitis. In chronic sinusitis there should be abnormal findings on CT or MRI. Some patients with chronic sinusitis might present with vague or insidious symptoms."
European Academy of Allergology and Clinical Immunology and the European Rhinologic Society (2012)[8]	"Rhinosinusitis in adults is defined as: • Inflammation of the nose and the paranasal sinuses characterised by two or more symptoms, one of which should be either nasal blockage/ obstruction/congestion or nasal discharge (anterior/posterior nasal drip): ± facial pain/pressure ± reduction or loss of smell and either • endoscopic signs of: o nasal polyps, and/or o mucopurulent discharge primarily from middle meatus, and/or oedema/mucosal obstruction primarily in middle meatus and/or • CT changes: mucosal changes within the ostiomeatal complex and/or sinuses" "Chronic rhinosinusitis with nasal polyps (CRSwNP): Chronic rhinosinusitis as defined above and bilateral, endoscopically visualised polyps in middle meatus." "Chronic rhinosinusitis without nasal polyps (CRSsNP): Chronic rhinosinusitis as defined above and no visible polyps in middle meatus, if necessary following decongestant."
British Society for Allergy and Clinical Immunology (2008)[9]	Diagnostic criteria for rhinosinusitis: "Major symptoms – two of the following, one to be: • Nasal congestion or obstruction • Nasal discharge (anterior or posterior) ± Facial pain or pressure ± Olfactory disturbance AND either Endoscopic signs (one or more of): • Polyps • Mucopurulent discharge from middle meatus • Oedema/obstruction at middle meatus OR Computerised Tomography (CT) signs"
American Academy of Otolaryngology – Head and Neck Surgery Foundation (2015)[10]	"[12] weeks or longer of [2] or more of the following signs and symptoms: • Mucopurulent drainage (anterior, posterior, or both), • Nasal obstruction (congestion) • Facial pain-pressure-fullness, or • Decreased sense of smell. AND inflammation is documented by one or more of the following findings: • purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region, • polyps in nasal cavity or the middle meatus, and/or radiographic imaging showing inflammation of the paranasal sinuses."

CRS: chronic rhinosinusitis; CRSsNP: chronic rhinosinusitis without nasal polyps; CRSwNP: chronic rhinosinusitis with nasal polyps; CT: computed tomography; MRI: magnetic resonance imaging.

Evaluation of patients for allergic disorders, immunodeficiencies, or both, may be indicated depending on the presence of associated symptoms.

Medical Treatment

Medical therapy for CRS, with or without polyps, is often multimodal, including nasal irrigation, topical and/or systemic corticosteroids, and/or antibiotic therapy.[11] Guidelines from the American Academy of Otolaryngology – Head and Neck Surgery (2015) have recommended the use of saline nasal irrigation, topical intranasal corticosteroids, or both, for symptom relief of CRS, on the basis of systematic reviews of randomized controlled trials (RCTs).[12] There is a specific recommendation against the use of topical and systematic antifungal therapies. The guidelines do not include a statement specifically addressing the use of systemic antibiotics for CRS; however, in the list of future research needs, the authors included: "Perform additional RCTs to clarify the impact of antibiotic therapy on CRS outcomes."

A systematic review by Rudmik and Sole (2015) evaluated the evidence for medical therapies for chronic sinusitis, excluding allergic fungal sinusitis.[1] Reviewers included 29 studies, with 12 meta-analyses (with a total of >60 RCTs), 13 systematic reviews, and 4 individual RCTs not included in any meta-analyses. Topical corticosteroids were associated, in multiple studies, with improved symptom scores, reduced polyp size, and decreased polyp recurrence after surgery. Saline nasal irrigation was associated, in multiple studies, with significant improvements in symptoms scores. There was some evidence that 2 systemic therapies (oral corticosteroids, doxycycline), both for 3 weeks, improved polyp scores in patients with CRS with nasal polyps. Long-term (>3 months) macrolide therapy was associated in 1 RCT with improved symptoms and QOL in individuals with CRS without nasal polyps, although other studies did not find a benefit with chronic macrolide use.

In 2014, an evidence-based review and consensus statement summarized a series of earlier evidence- based reviews with recommendations related to CRS.[13] This review concluded that both saline irrigation and topical corticosteroids are well-supported by the available published literature for treatment of CRS, with and without nasal polyps. For CRS with polyps, the evidence demonstrated short-term improvement in symptoms after short-term oral corticosteroid treatment. For CRS with or without nasal polyps, a small number of RCTs have shown improvement in nasal endoscopy scores and some symptoms with oral macrolide therapy. However, for CRS with or without nasal polyps, there is very limited evidence on the use of nonmacrolide oral antibiotics.

A 2011 Cochrane review of studies comparing systemic antibiotics with placebo for CRS in adults identified 1 study (N=64 patients) judged to be at high risk of bias.[14] Reviewers concluded: "Further good quality trials, with large sample sizes, are needed to evaluate the use of antibiotics in chronic rhinosinusitis."

Surgical Treatment

The goals of surgery for CRS include removing polyps and debris that may be sources of inflammatory mediators and prevent the effective delivery of local medical therapies. In

addition, to varying degrees, surgical techniques involve the creation of open sinus cavities, usually via dilation of the sinus ostia, to permit better drainage from the sinus cavities and more effective delivery of local therapies.

Techniques for functional endoscopic sinus surgery (FESS), in which an endoscope is used to access the sinus cavities and varying degrees of tissue are removed and the sinus ostia are opened, have evolved since the development of the nasal endoscope in the 1960s. FESS has largely replaced various open techniques for CRS (e.g., Caldwell-Luc procedure), although open procedures may have a role in complicated sinus pathologies (e.g., endonasal tumors).

FESS encompasses a variety of degrees of sinus access and tissue removal, and is described based on the sinuses accessed. The Draf classification is used to describe degrees of endoscopic frontal sinusotomy (see Table 2)

Table 2. Draf Classification for Endoscopic Frontal Sinusotomy

Type	Description
Draf I	Anterior ethmoidectomy without altering frontal sinus ostium
Draf IIA	Removal of ethmoid cells that extend into frontal sinus
Draf IIB	Removal of frontal sinus floor between the middle turbinate and the lamina papyracea
Draf III[a]	Removal of frontal sinus floor from orbit to orbit with contiguous portions of the superior nasal septum

[a] Modified Lothrop procedure.

FESS can also be used to access the ethmoid sinuses (ethmoidectomy, which may involve creation drainage into the maxillary sinuses [maxillary antrostomy]).

Outcomes

To quantify the severity of CRS and to assess treatment response, various outcomes measures can be used, including patient-reported QOL measures, radiologic scores, and endoscopic grading.

The Lund-McKay scoring system uses radiologist-rated information derived from computed tomography scans regarding opacification of the sinus cavities, generating a score ranging from 0 to 12.[15,16]

Several disease-specific patient-reported QOL scores have been used. Commonly used is the Sino-Nasal Outcome Test-20 (SNOT-20), a validated questionnaire, in which patients complete 20 symptom questions on a categoric scale (0 [no bother] to 5 [worst symptoms can be]). Average rankings can be reported over all 20 symptoms, as well as by 4 subclassified symptom domains. The SNOT-22 is a variation of the SNOT-20 that includes 2 additional questions ("nasal obstruction" and "loss of smell and taste"). The minimal clinically important difference for the SNOT-22 has been estimated to be 8.9 points.[17]

Additionally, QOL may be reported based on overall health-related QOL scores, such as the 36-Item Short-Form Health Survey (SF-36). The SF-36 consists of 8 scales on various health domains, which are transformed into a scale ranging from 0 to 100 (100 corresponding to best health).

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REGULATORY STATUS

Functional endoscopic sinus surgery is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

IV. RATIONALE

TOP

SUMMARY OF EVIDENCE

For individuals with CRS with or without nasal polyposis who receive FESS, the evidence includes randomized controlled trials and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A small number of trials, with methodologic limitations, generally have not reported clinically significant differences in symptom improvement with FESS compared with medical therapy. Two Cochrane reviews evaluating FESS for CRS with and without nasal polyposis have reported that FESS can be accomplished safely, but clinical trials have not demonstrated significant improvements with FESS compared with standard medical therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VI. DISCLAIMER

TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®							
31237	31238	31239	31240	31241	31253	31254	31255
31256	31257	31259	31267	31287	31288	31294	

ICD-10-CM Diagnosis Code	Description
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J32.4	Chronic pansinusitis
J32.8	Other chronic sinusitis

VIII. REFERENCES

TOP

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32, Blue Cross Blue Shield Association Medical Policy Reference Manual.7.01.155, Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis. February 2019.

IX. POLICY HISTORY

Top

MP 1.152	**CAC 1/30/18** New policy, adopted from BCBSA. Use of functional endoscopic sinus surgery in the treatment of chronic rhinosinusitis is considered medically necessary when criteria is met.
	2/14/19 Consensus review. No changes to the policy statements. References reviewed. Rationale revised.

Top